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Medical Product Safety

Lead Agency: Food and Drug Administration

Contents

Goal

Ensure the safe and effective use of medical products.

Overview

Medical products—which include drugs, biological products, and medical devices—provide great public benefit. Although marketed medical products are required to be safe, this does not mean they have zero risk. A safe product has reasonable risks, given the magnitude of the benefit expected from the product and the alternatives to its use. Thus the choice to use a medical product involves balancing its benefits with the potential risks of using it. The comparative evaluation—which involves weighing the benefits (positive effects) and risks (potential harm) of various medical options for treatment, prophylaxis, prevention, or diagnosis—is an essential part of determining product safety. Evaluation is done during research and development on new medical products or procedures (such as surgery) or by a regulatory authority deliberating the approval or withdrawal of a product or some intermediate action, by a physician on behalf of a patient or by the patient. Such weighing, whether implicit or explicit, is at the heart of decisionmaking in medicine and health care.

The United States has an elaborate system to maintain this benefit-risk balance by making sure that products are developed, tested, manufactured, labeled, prescribed, dispensed, and used in a way that maximizes benefit and minimizes risk. This complex system involves several key players: manufacturers that develop and test medical products and submit applications for marketing approval to the Food and Drug Administration (FDA); FDA, which has an extensive premarketing review and approval process and uses a series of postmarketing programs to gather data on and assess risks; the health care delivery system; and patients, who rely on the health care system and providers to provide them with needed interventions while protecting them from injury. Regrettably, however, this elaborate benefit-risk system and its subsystems lack the integration needed to ensure optimal public health and safety.

Sources of risk. It is widely accepted that enormous benefits can be gained from using medical products. Yet while most are well tolerated, producing only minimal side effects or a low rate of adverse events, some products can be very toxic, producing a high rate of complications from side effects. It is estimated that millions of adverse events associated with the use of medical products occur each year; many of these are serious and may result in death.[1]

Federal oversight of a medical product's benefits versus risks continues well beyond the initial marketing of a product. Once a medical product is approved for marketing, the safety of the product continues to be monitored by FDA, which

collects and analyzes reports of product experience. As more products are approved for marketing, postmarketing surveillance becomes increasingly important. Through a program called MEDWATCH, FDA's Medical Products Reporting Program and Safety Information, health care professionals, patients, and consumers can report serious adverse events and problems associated with medical products to FDA, the manufacturer, or both. MEDWATCH also accepts reports of medication errors or potential errors. Partners include health professionals, consumers, and other appropriate health-related organizations or commercial interests that actively disseminate information on the critical importance of monitoring and reporting serious adverse events and product problems, along with information on how to report directly to the FDA. These partners also provide a 'multiplier effect,' in which MEDWATCH partners rapidly disseminate new FDA-related product safety information back to their membership.

The growing complexity of medical technology, coupled with economic pressures and organizational change within health care institutions, increases the potential for unanticipated and unintended consequences in using medical devices. These changes demand that postmarket surveillance move from passive surveillance to a proactive strategy that includes understanding how organizations encounter medical devices, how problems are perceived and reported, and which characteristics of the health care system contribute to a given event. A safer patient environment can be created if increased efforts are made to identify product failures and errors before patients are injured.

Beyond the individual level of risk management (for example, patients and health care providers), managing risk must be targeted at the organization level. For example, user facilities such as hospitals, long-term care facilities, ambulatory surgical, outpatient treatment, and outpatient diagnostic centers, are required to report errors related to medical devices. By law, these facilities are required to report any death to FDA and to the manufacturer of the device within 10 working days. Any serious illness or injury also must be reported by the user facility to the manufacturer within 10 working days or, if the manufacturer is unknown, the report should be sent to FDA. Further, FDA encourages user facilities to report product or device malfunctions (for example, intravenous catheter defects) that do not result in death or serious injury directly to the manufacturer.

Efforts to manage risk at the community, national, and global levels present the most difficult public health challenges. The introduction of hepatitis B surface antigen screening and the change to an all-volunteer blood donor population in the mid-1970s resulted in substantial reductions in transfusion-transmitted viral hepatitis. This success, however, was overshadowed by the unexpected emergence of a new blood-borne pathogen, human immunodeficiency virus (HIV). Since its initial recognition in the early 1980s, more than 8,000 persons have been diagnosed with transfusion-associated acquired immunodeficiency syndrome (AIDS), and approximately half of the United States hemophiliac population has been infected with HIV. The HIV epidemic remains a potent reminder of the Nation's vulner-

ability to emerging agents and the tragic repercussions they can exact on those who depend on life-saving blood and blood products.

FDA takes primary responsibility for ensuring blood safety and has taken the lead in recent efforts. Today, improvements in donor screening, serologic testing, and viral inactivation procedures have made the U.S. blood supply one of the safest in the world. Nevertheless, many additional steps can be implemented by FDA, industry, consumers, and blood donor volunteers to go further. Since 1998, the Department of Health and Human Services has coordinated the efforts of the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and FDA, with cooperation from other government agencies, in a Blood Action Plan. Consumer and donor confidence are important factors in maintaining a safe blood supply and Healthy People 2010 objectives reflect those concerns and incorporate a science-based approach to expanding the blood supply and enhancing its safety.

Management of medical product risk. In general, the sources of medical product risks can be thought of as falling into four categories: (1) product defects; (2) known side effects, both avoidable and unavoidable; (3) medication or device errors; and (4) remaining uncertainties.[2] Because each type of risk has a different source, effective management of each is likely to be different.

Product defects. Historically, product defects have been an important source of medical product-associated injuries. In the case of pharmaceuticals, product defects usually include the lack of potency and the lack of purity of drugs. A significant portion of resources is currently devoted to regulating product quality. Research, surveillance, quality systems also called *current good manufacturing practices*, and inspections form the cornerstone of FDA efforts to minimize product defects.

Known side effects. When using a drug or other medical product, a patient runs the risk of experiencing reactions resulting from the product's interaction with the body. For pharmaceuticals, these reactions are commonly termed *side effects*. They are usually identified in a product's package insert as possible risks. Known side effects are the source of the majority of injuries and deaths resulting from product use.

Some known side effects are often predictable and avoidable. To avoid them, the health care practitioner must select the best treatment and plan appropriate measures to manage the risks. For example, when prescribing certain prescription medications that are renal toxic (toxic to the kidneys), practitioners need to ensure that their patients are well hydrated or calculate dose adjustments to reduce the risk of toxicity or kidney failure. A medical practitioner can choose the wrong therapy for a specific condition (for example, using antibiotics for viral infections). Alternatively, a practitioner may prescribe the appropriate therapy but fail to individualize the therapy or monitor the patient for signs of toxicity. Examples

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of avoidable side effects include the consequences of known drug-drug interactions or prescribing an inappropriate dosage for elderly persons.

In many cases, known side effects are unavoidable because they can occur even if a product is used appropriately. Although estimates vary, the overall human and economic costs of unavoidable side effects are high.[3] The risk of experiencing such side effects is the inevitable price of the benefits of treatment. Examples of common, predictable, usually unavoidable side effects include superinfection following antimicrobial chemotherapy, fatigue and depression from interferon use, and bone marrow suppression from chemotherapy. For the successful management of these risks, both the practitioner and patient must be fully aware of the risks involved in treatment, agree to the treatment, and provide careful patient monitoring to detect early symptoms of known side effects.

Medication or device errors. A medication or device error involves the incorrect use of a prescribed product or incorrect operation or placement of a medical device. Errors also involve unintended substitution of the wrong product for the prescribed product. Errors can occur for example, when a confusing product name results in the wrong product being dispensed, or when inattention results in an overdose of an intended drug. Substantial numbers of injuries and deaths occur annually because of medication or device errors.[4] In general, medication and device errors are believed to result from problems intrinsic to the health care system. That is, these errors often are the result of a sequence of errors within the health care system. For example, a physician's poor handwriting on the prescription pad and unclear or confusing prescription drug labeling result in pharmacists' misreading prescriptions and labeling and filling prescriptions with the wrong medications. Such errors are not totally preventable, but they can be minimized through enhancements aimed at integrating the overall health care system.

Remaining uncertainties. Given current scientific and medical knowledge, it is not possible to learn everything about the effects of a medical product. For example, new information about long-marketed products may become available. Therefore, a degree of uncertainty always exists about both the benefits and risks of medical products, including unexpected side effects, long-term effects, effects of off-label use, and effects in populations not studied before marketing.

Managing risk and medical product safety is a matter of continuously developing information. A comprehensive risk management system requires risk communication. Thus, effective risk communication demands that risk information be translated into words and formats that are readily understood by practitioners, caregivers, and patients. For example, U.S. Pharmacopeia (USP) and FDA have adopted the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Taxonomy for Medication Errors in order to report, track, and benchmark medication error data in a standardized format for hospitals nationwide. In this risk communication strategy, FDA and USP are expected to provide a nationally projected measure of errors grouped according to categories established by the NCC MERP.

Because national data systems will not be available in the first half of the decade for tracking progress, three subjects of interest are not addressed in the Healthy People 2010 Medical Product Safety objectives. Representing a research and data collection agenda for the coming decade, the topics are related to the record practices of health care professionals, plasma manufacturing, and data analysis. The first topic covers health care professionals who record their patient's use of botanicals, dietary supplements, and other alternative products to identify the risks of using these products in combination with conventional drugs and biologics. The second topic addresses the development and application of effective methods for complete inactivation or removal of pathogens from plasma, blood, and blood products. The third involves the proportion of new medical products that have had pre- and postmarketing clinical data analyzed for gender differences.

Disparities

Certain groups are particularly vulnerable to poor health outcomes because they are exposed to both socioeconomic and age-related physiological stress factors that interact synergistically. People aged 65 years and older, for example, take the greatest number and quantity of medications.[5] Of elderly patients taking three or more prescription drugs for chronic conditions, more than one-third are rehospitalized within 6 months of discharge from a hospital, with 20 percent of those readmissions due to drug problems.[6] Twenty-eight percent of hospitalizations of older people are due to noncompliance with drug therapy and adverse events.[7] Adverse drug events rank fifth among the top preventable threats to the health of older people in the United States, after congestive heart failure, breast cancer, hypertension, and pneumonia.[8] Moreover, 32,000 adults aged 65 years and older suffer hip fractures each year as a result of falls associated with the use of psychotropic drugs, which are used to treat the patients' underlying medical condition.[9] Moreover, growth in these numbers is expected, given the increasing number and potency of drug products being marketed and the increasing percentage of the population that is elderly.

Data collection systems do not exist that would allow analysis of disparities in adverse events among different population groups. Because there is a need to look at select populations, which are diverse in race, ethnicity, socioeconomic status, and area of residence, it is likely that data will be needed from many provider organizations.

Another example of a common variable that predisposes individuals to vulnerability and poor health outcomes is literacy. Literacy disparities are of concern because low-literacy patients cannot be "empowered" consumers.[10] Further, patients who do not understand health professionals' instructions will not receive good-quality care. Finally, because health literacy problems are concentrated in populations that depend on public programs for their medical care, an education effort may be required to inform public assistance patients about how to understand the proper use of their medicines. To reach all people effectively, information must be provided in a variety of formats and reading levels. (See Focus Area 7.

Educational and Community-Based Programs and Focus Area 11. Health Communication.)

Opportunities

Although medical products provide benefits, they also can cause injury and harm. FDA and other participants act in ways to maximize the benefits and minimize the risks associated with using medical products. Often, these actions are insufficiently integrated. A common goal of maximizing benefits and minimizing risks could be greatly advanced if the participants work together within an integrated framework. An integrated benefit-risk management framework, if adopted, would contribute to improving risk communication and risk confrontation.

Risk communication. The health care industry has experienced tremendous growth and demand in building an infrastructure driven by technology. For example, elaborate information technology (IT) software programs, which link to huge databases, allow access to a vast amount of valuable information for pharmacists and other health care professionals, health care organizations, and consumers. The information in these systems is used to improve patient care, design better health care methods, improve operations, and enhance organizational planning. Many groups benefit from sharing information between different components of health care, including patients, providers, insurance companies, medical equipment companies, pharmaceutical companies, hospitals, and data processing and health research corporations. Technology is available to integrate the different components of health care, but its use today is minimal except in select health care settings. Therefore, it would be advantageous to encourage upgrades to present technology systems and links to other integrated technology systems to improve patient care, always keeping in mind, of course, patient confidentiality.

Evolving automation offers the possibility of placing the entire patient record into an electronic format. Electronic formats offer the possibility of automatically and instantaneously checking any new therapy for incompatibilities with the products, appropriate indications and dosing range, and the patient's current therapies and contraindications (for example, allergies or reduced hepatic or renal function). Electronic formats also offer the possibility of looking at diagnoses and seeing whether patients (or in cases of children, their parents) have been exposed to existing therapies in the past.

Further, as IT systems become more advanced and sophisticated, there is a growing need to ensure and protect patient confidentiality. Health plans, providers, and pharmacy benefit managers have long recognized the importance of maintaining the confidentiality of patient-identifiable medical information. There is a vast potential for information sharing between different components of health care if the confidentiality issues can be overcome. Legislation to protect patients from the inappropriate disclosure of their medical information will be essential to the development of systems that are designed to protect their health and welfare.

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One final consideration for effective risk communication is to provide information about medical products that is useful for patients, consumers, and practitioners. (See Focus Area 11. Health Communication.) Effective risk communication requires information presented in words and formats readily understood by practitioners, caregivers, and patients. This information must be disseminated in a timely fashion and incorporated into clinical practice that is aimed at altering behaviors. Since March 1999, Federal regulations have required over-the-counter (OTC) drug manufacturers to follow a specific format for the labeling of OTC drugs.[11] The format is intended to assist consumers in reading and understanding OTC drug product labeling so that they can use these products safely and effectively.

Risk confrontation. Determining the acceptable level of risk should occur in a larger context.[12] This activity is characterized as risk confrontation: community-based problem solving that actively involves stakeholders in the decisionmaking process.[13] This definition implies that social and community values are at least as important as the technical judgments of professionals and should be included in the determination of acceptable risk.

Science provides only a statistical assessment of risk; it cannot determine its acceptability. Affected communities may differ from regulatory agencies in how they value either risks or benefits. They also may judge differently the amount of uncertainty that is tolerable. Advocacy groups for patients with various diseases, most notably AIDS and cancer, have shown over the past several years that it is impossible to accurately assess the acceptability of risks in light of the potential benefits without the input of the affected community. Although some advocates for patients with life-threatening illnesses are willing to accept a high degree of risk to gain the benefits of new products, other advocacy groups, such as those against mandatory vaccination, feel that no risk is acceptable.

To obtain community input, FDA has engaged in multiple outreach efforts with external stakeholders, soliciting their ideas, opinions, and concerns regarding the safe use of medical products. In the context of determining risk, for example, fostering open public discussions is critical to enhancing participants' practical understanding and illuminating practice choices in the risk decision process. A carefully prepared summary of scientific information will not give participants in the risk decision the understanding they need if that information is not relevant to the decision to be made. It is not sufficient to get the science right; an informed decision also requires getting the right science, that is, directing the scientific effort to the issues most pertinent to the decision.

Interim Progress Toward Year 2000 Objectives

The Healthy People 2000 objective on linked computer systems has been met. In 1995, 98 percent of pharmacies were using computers. Data for providers who review medications for older patients and for the proportion of patients who

receive verbal and written information for new prescriptions from prescribers and dispensers show progress. The proportion of adverse event drug reports voluntarily sent to FDA that are regarded as serious has declined slightly and is moving away from the target.

Note: Unless otherwise noted, data are from Centers for Disease Control and Prevention, National Center for Health Statistics, *Healthy People 2000 Review, 1998-99.*

Medical Product Safety

Goal: Ensure the safe and effective use of medical products.

Number	Objective
17-1	Monitoring of adverse medical events
17-2	Linked, automated information systems
17-3	Provider review of medications taken by patients
17-4	Receipt of useful information from pharmacies
17-5	Receipt of oral counseling from prescribers and dispensers
17-6	Blood donations

17-1. (Developmental) Increase the proportion of health care organizations that are linked in an integrated system that monitors and reports adverse events.

17-1a. Health care organizations that are linked in an integrated system that monitors and reports adverse events associated with medical therapies.

17-1b. Health care organizations that are linked in an integrated system that monitors and reports adverse events associated with medical devices.

Potential data sources: Office of Postmarketing Drug Risk Assessment (OPDRA), MEDWATCH, and Manufacturer and User Device Experience (MAUDE) Database, FDA.

Collaboration between Federal authorities and researchers with pharmacoepide-miological databases can be helpful in monitoring suspected associations between specific drug exposures and specific adverse events and in estimating such risk. Linked databases could provide immediate access to existing data sources with the capability of providing assessments of study feasibility, responding to specific drug safety questions within a few weeks, and providing a complete analysis of those questions deemed feasible within a few months. Databases should be able to provide exposure data on new molecular entities (those approved within the past 5 years in the United States), to perform feasibility studies of multiple drugs or multiple outcomes, to identify adverse drug events that occur infrequently (that is, at rates lower than can be detected in clinical trials), and to provide data and preliminary analyses within a very short time frame (2 to 4 weeks, depending on the problem).

To identify unknown events more rapidly, there must be an enhanced program of communication for health professionals nationwide that builds on the work of MEDWATCH, encouraging the recognition of unique and rare events. To evaluate and quantify newly identified events, there must be a significant population base under close electronic surveillance for indicators of adverse reactions. A relatively large number of persons (estimated around 20 million) is necessary because so many persons are lost to followup when they move from one provider organization to another. If medical records are ultimately transferred from one provider to another, a number smaller than 20 million may suffice to allow outcomes to be linked with earlier therapies. While maintaining confidentiality, there must be a system for accessing the original patient record.

Staff-model health maintenance organizations (HMOs) are providing health care services to a greater proportion of patients and, therefore, would be a good target for linked data systems capable of picking up rare adverse events and signals in patient populations. HMOs and other health care providers capable of producing complete patient records should be particularly targeted to participate in this de-

velopment. At present, there is no standard format for these records. HMOs may have different systems at each site or, where organizations have come together to form a single large organization, each remnant of the original organizations may have preserved its own medical record system. HMOs might be encouraged to see safety surveillance data as a product, which could be purchased by the Federal Government and industry after appropriate protection of patient privacy. Alternatively, large employers or government agencies might use their purchasing power to demand safety surveillance as a deliverable under managed care contracts.

The Safe Medical Device Acts of 1990 and 1992 mandate reporting of device-related deaths to FDA and device-related deaths and serious injuries to manufacturers. The program has shown only limited success. Research on the program indicates that the quantity and quality of data received could be enhanced through training and education for end users of medical devices regarding how to report device-related deaths and serious injuries to manufacturers, additional assurance of the protection of data submitted, and regular, timely feedback. The research also suggested that a medical surveillance network could improve the protection of patients and device users by reducing the likelihood of medical-device-related adverse events. The system should collect high-quality data on adverse medical events; analyze the data to identify newly emerging device problems and changes in device use; disseminate data on such problems in a timely manner to concerned parties; and apply the knowledge gained from the reported data to the device approval process and to prevention and control programs.

17-2. (Developmental) Increase the use of linked, automated systems to share information.

17-2a. By health care professionals in hospitals and comprehensive, integrated health care systems.

17-2b. By pharmacists and other dispensers.

Potential data sources: National Survey of Pharmacy Practice in Acute Care and Survey of Managed Care and Ambulatory Care Pharmacy Practice in Integrated Health Systems, American Society of Hospital Pharmacists (ASHP).

Automated information systems enable pharmacists in hospitals, HMOs, and Department of Veterans Affairs (VA) settings to review a patient's medical record, pharmaceutical history, allergies and contraindications to medications, blood chemistries and microbiological drug sensitivities, and treatment schedule files. These systems help administrative personnel in various work settings to process prescription claims and payments, measure the quality of health care, perform cost analyses, provide drug information, perform pharmacoenonomic analyses, and purchase pharmaceutical products.

Dispensers of prescription medications use linked systems to provide warnings about dosing errors and potential adverse events among medications dispensed by different sources to individual patients. In 1993, 95 percent of pharmacies used

computer systems.[14] Advances in computer technology should facilitate information sharing in a way that helps health care professionals and researchers link drug products and outcomes in order to benefit individual patients and to discover previously unknown adverse reactions.

Computerization of the medication use process can help prevent prescribing, dispensing, and administration errors. The documented value of direct order entry continues to be confirmed.[15] A recent study demonstrated that replacing handwritten medication orders with a computerized physician order entry system led to a 54 percent reduction in serious medication errors.[16] In addition, the National Patient Safety Foundation at the American Medical Association (AMA) has identified direct computerized order entry as one of the best practices for preventing adverse drug events.[15]

17-3. (Developmental) Increase the proportion of primary care providers, pharmacists, and other health care professionals who routinely review with their patients aged 65 years and older and patients with chronic illnesses or disabilities all new prescribed and over-the-counter medicines.

Potential data sources: National Hospital Ambulatory Medical Care Survey (NHAMCS) and National Ambulatory Medical Care Survey (NAMCS), CDC, NCHS; Survey on Prescription Drug Issues and Usage, AARP; Physician Survey Under the Medication Error Reduction Initiative.

Adults aged 65 years and older account for less than 15 percent of the population, but they use about one-third of all retail prescriptions.[5] This population also purchases at least 40 percent of all nonprescription medicines.[5] Further, older adults are more likely to suffer from multiple chronic diseases and, as a result, may routinely visit multiple physicians, each of whom may be unaware of other medicines that have been prescribed.

In 1998, an AMA House of Delegates report urged physicians to incorporate medication reviews as part of routine office-based practice. The report also encouraged physicians to discuss compliance with the drug regimen with their patients and to inquire about the beneficial or adverse effects of drug therapy during followup office visits. AMA's House of Delegates report suggests that physician medication reviews are critically important with long-term therapy.

17-4. Increase the proportion of patients receiving information that meets guidelines for usefulness when their new prescriptions are dispensed.

Target: 95 percent of patients.

Baseline: Data will be available January 2000.

Target setting method: Target setting method to be established when data are available.

Data source: Patient/Consumer Medication Information Survey, FDA.

A 1992 survey conducted by FDA of the amount of information received by consumers found that 14 percent of people received information about prescription drugs from prescribers and 32 percent from pharmacists.[17] These percentages do not reflect the usefulness of the information received because no content analyses were performed on the informational materials reported in the survey. Congress enacted legislation in 1996 that called on the private sector to develop a plan whereby 95 percent of persons would receive useful written information with their prescriptions by 2006. The Department of Health and Human Services approved guidelines in the Action Plan for the Provision of Useful Prescription Medicine Information in January 1997. In accordance with the plan, patient information materials were to be evaluated in 1999 and 2000. (See Focus Area 28. Vision and Hearing.)

17-5. Increase the proportion of patients who receive verbal counseling from prescribers and pharmacists on appropriate use and potential risks of medications.

Target and baseline:

Objective	Increase in Patients Receiving Oral Counseling From:	1998 Baseline	2010 Target
		Percent	
17-5a.	Prescribers	24	95
17-5b.	Pharmacists	14	95

Target setting method: 296 percent improvement for prescribers and 579 percent improvement for pharmacists. (Better than the best will be used when data are available.)

Data source: National Survey of Prescription Drug Information Provided to Patients, FDA.

Patients and their caregivers should be fully informed about the appropriate use and the risks of newly prescribed prescription medicines. The physician (or other prescribing health care professional) should initially discuss this information with the patient. The next opportunity for verbal counseling arises at the pharmacy. In both settings, written information about the medicine may be conveyed but is most effective when supplemental to verbal counseling. Elements of verbal counseling should include not only how much and how often to take the medication, but also appropriate risk information, including precautions to take and the relevant side effects of the medication.

Participants in a 1997 national symposium on verbal counseling, sponsored by national pharmacy and pharmacist organizations, gave the highest rankings to the following reasons for such low counseling levels: patients do not understand what and why they need to know about their medicines; patients do not demand or expect counseling services from the pharmacists; and patients and payors do not see the value of counseling.[17] These findings suggest that a high number of pharmacists believe that patients do not understand what and why they need to know about their medications and, therefore, do not provide needed counseling. Since 1997, the American Pharmaceutical Association has maintained a policy stating that pharmacists should provide drug-related information to their patients in face-to-face oral consultations, supplemented by written or printed material, or any other means best suited to an individual patient's needs.[18]

The National Council on Patient Information and Education (NCPIE) advocates that health care professionals anticipate consumers' desire for medication information but also recognize their possible reluctance to ask questions. NCPIE has developed several educational campaigns to facilitate question-asking behaviors by consumers and support information-giving behaviors by health care professionals.

17-6. Increase the proportion of persons who donate blood, and in so doing ensure an adequate supply of safe blood.

Target: 8 percent.

Baseline: 5 percent of the total population donated blood in 1994.

Target setting method: 60 percent improvement.

Data source: American Association of Blood Banks.

> **Data for population groups currently are not collected.**

FDA assumes primary responsibility for the safety of the Nation's blood supply. Blood availability, however, is restricted by, among other issues, the number of donors who qualify to give blood. Approximately 5 percent of the population in the United States donates blood once or twice a year. Recruitment of a larger percentage of the population would increase the availability of blood and blood products. Public awareness of the benefits that blood and blood products provide to cancer patients and others in need could serve to elicit a more generous response. Educational campaigns that address underlying public fears regarding the safety of blood donation procedures could also help. Increasing the donor pool would benefit the overall health of the Nation and remove donor incentives that border on remuneration.

Related Objectives From Other Focus Areas

1. Access to Quality Health Care

1-3.   Counseling about health behaviors

3. Cancer

3-10.   Provider counseling about preventive measures

3-12.   Colorectal cancer screening

4. Chronic Kidney Disease

4-8.   Medical therapy for persons with diabetes and proteinuria

5. Diabetes

5-17.   Self-blood glucose monitoring

7. Education and Community Based Programs

7-7.   Patient and family education

7-8.   Satisfaction with patient education

7-9.   Health care organization sponsorship of community health promotion activities

7-11.   Culturally appropriate community health promotion programs

9. Family Planning

9-3.   Contraceptive use

9-4.   Contraceptive failure

9-5.   Emergency contraception

11. Health Communication

11-1.   Households with Internet access

11-2.   Health literacy

11-3.   Research and evaluation of communication programs

11-4.   Quality of Internet health information sources

11-5.   Centers for excellence

11-6.   Satisfaction with providers' communication skills

12. Heart Disease and Stroke

12-10.   High blood pressure control

12-12.   Blood pressure monitoring

13. HIV

13-6.   Condom use

13-7.   Knowledge of serostatus

15. Injury and Violence Prevention

15-10.   Emergency department surveillance systems

15-13.   Deaths from unintentional injuries

23. Public Health Infrastructure

23-1.   Public health employee access to Internet

23-2.   Public access to information and surveillance data

23-3.   Use of geocoding in health data systems

Terminology

(A listing of all abbreviations and acronyms used in this publication appears in Appendix K.)

Adverse drug experience (ADE): Any adverse event (defined below) associated with the use of a drug in humans, whether or not considered drug related. These include the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from a result of a drug overdose, whether accidental or intentional; an adverse event occurring from a drug abuse; an adverse event occurring from drug withdrawal; and any failure of a drug's expected pharmacological action.

Adverse event: Undesirable result from the use of a medical product. Terms used to describe such an event include adverse drug reaction (ADR), adverse experience, and adverse effect. For the purposes of Healthy People 2010, the term *adverse event* is used in most cases to avoid confusion.

Consumer: An individual who consumes or acquires medical products, such as nonprescription (over-the-counter) medicines or nonprescription medical devices.

Medical device: An instrument, apparatus, implement, machine, implant, or other similar or related article intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.

Medical product: Any prescription and nonprescription drug, device, or biological product intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of the disease.

Medication or device error: A preventable event that may cause a medication or device to be used inappropriately and thus may harm a patient. Harm can occur while the medical product is being used by a health care professional, patient, or consumer.

Off-label use: Uses other than those for which the product is approved.

Patient: An individual who is under medical treatment.

Pharmacoepidemiological database: A computerized database for capturing and manipulating data associated with the collection, analysis, and communication of drug or other therapeutic product risk information.

Risk assessment: Estimation and evaluation of risk.

Risk communication: Interactive process of exchanging risk information.

Superinfection: A new infection complicating the course of antimicrobial therapy by an organism different from that which caused the initial infection. The new infection results from invasion by bacteria or fungi resistant to the antimicrobial in use.

U.S. Pharmacopeia (USP): Organization that promotes the public health by establishing and disseminating officially recognized standards of quality and authoritative information for the use of medicines and other health care technologies.

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